UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,457	09/19/2003	Harischandra K. Mhatre	HKM-01	8334

7590 12/27/2005

OLSON & HIERL, LTD.
36th Floor
20 North Wacker Drive
Chicago, IL 60606

EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,457	MHATRE, HARISCHANDRA K.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2003 and 20 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☒ Claim(s) *20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/20/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The preliminary amendment filed 5/20/04 has been entered. The changes to the specification have been approved by the examiner.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "pivot axis 76" mentioned on page 10, line 29 is not shown in the figures.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "40" has been used to designate both "longitudinal axis 40" on page 7, line 13 and shown in Fig.4, and "diameter 40" on page 12, line 27. The examiner suggest deleting "40" after "diameter".

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:

a) On page 9, line 12, "window 48" must be changed to --window 49--.

b) On page 11, line 2, "75B" must be changed to --57B--.

c) On page 12, line 27, it appears from Fig. 2 that "distance y" should be --distance Y--.

d) On page 13, line 6, "wall 32" must be changed to --wall 46--.

e) On page 13, line 10, "and 64" should be deleted because "64" is not shown in the drawings and because "63" has been used to designate the inner straight edge portion for both leaflets 31 and 32.

f) On page 13, line 14, "and 62" should be deleted because "62" is not shown in the drawings and because "61" has been used to designate the outer rounded edge portion for both leaflets 31 and 32.

Appropriate correction is required.

Claim Objections

5. Claims 1 and 7 are objected to because of the following informalities:

a) In claim 1, line 7 of (g), --a-- should be inserted after "define".

b) In claim 7, line 7 of (g), --a-- should be inserted after "define".

c) In claim 7, line 8 of (g), "configurations" should be changed to --configuration--.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 2, 4-9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mhatre et al. (USPN 5,326,372, as cited in applicant's IDS) in view of Bicer (USPN 5,061,278, as cited in applicant's IDS).

Mhatre et al. disclose a prosthetic heart valve assembly with all the elements of claims 1 and 7, but are silent to groove means defined in the side wall portions adjacent to the bearing block receiving window and the window perimeter portions having groove means defined therein located adjacent to said separate bearing block perimeter edge portions when the separate bearing block is so seated against the window edge perimeter portions. See Figures 5, 5A and 8A for an annular structure (50) having a longitudinal axis (70), generally cylindrical medial sidewall portions defining a central passageway therethrough, and outwardly flanged terminal rim portions, wherein the side wall portions define an integral bearing block (58) and a generally diametrically opposed bearing block receiving window (62) with radially inclined window perimeter edge portions. The word "integral" is defined in Merriam-Webster Online Dictionary as "*essential to completeness: constituent*". Because the bearing blocks (58) are essential to completeness and are constituents of the prosthetic heart valve assembly, one of the bearing blocks, when inserted within the window, is considered the radially thickened integral bearing block (58). See Figure 8A and column 11, lines 57-64 for a separate bearing block

(other 58) with radially inclined block perimeter edge portions for seating in the bearing block receiving window (62), wherein the separate bearing block (58) and the bearing block receiving window (62) have cooperating respective perimeter portions and whereby the separate bearing block (58) is received within and sealingly engaged within the bearing block receiving window (62). See Figure 8A for the integral and separate bearing blocks (58) each having a flat interior face (60) that has defined therein a pair of circumferentially spaced bearing recesses/cavities (59), and Figure 5 for the interior faces (60) being parallel to each other and to the longitudinal axis. See Figures 5 and 7 for a pair of leaflets (51), each one disposed across the passageway and having a generally flattened body portion defined by a perimeter that includes a generally arcuately extending outside edge region (56), a straight inside edge region (75), and a pair of outwardly extending, integral, peripherally rounded, ear-like projections (54) each located between a different adjacent pair of the outside edge region (56) and the inside edge region (75). See Figure 5A for the interrelationship between the leaflets (51), the annular structure (50), and the bearing blocks (58) being such that the leaflets are each locatable across a different but adjacent portion of the passageway with each ear-like projection (54) being pivotably associated with different one recess/cavity (59) in each of the bearing blocks (58) and with the leaflets being pivotable in response to fluid pressure (53) applied on an upstream side of the passageway, whereby the leaflets (51) in combination are adapted to extend across and close the passageway and thereby define a valve closed configuration and also to pivot and open the passageway and thereby define a valve open configuration. Bicer teaches an artificial heart valve with bearing blocks (22) inserted into bearing block receiving windows (28), wherein a groove means (25) is defined in the window perimeter portion of the sidewall (18) and a circlip

(24) is demountably positionable in the groove means (25) in order to retain the bearing blocks (22). See Figures 1-3 and columns 6-7, lines 66-5. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bicer to modify the prosthetic heart valve assembly of Mhatre et al. by replacing the retaining metal band (71) with groove means (25) in the window perimeter portion of the sidewall and circlip (24) positioned therein. Because the two circlips used are much smaller than the metal band, such replacement would advantageously reduce the overall weight of the prosthesis.

Claims 2 and 8, see column 5, lines 58-65 for the annular structure (50), separate bearing block (58), and leaflets (51) each having surface portions comprised of pyrolytic carbon.

Claims 4 and 11, see Figure 5 for in the valve closed configuration, the straight inside edge portion (75) of each leaflet (51) is in adjacent, contacting relationship with the other, and the arcuately extending outside edge region (56) of each leaflet is in adjacent contacting relationship with a different interior side wall portion (52) of the annular structure (50).

Claim 5, see Figure 5A for the extent of pivotal opening and closing movement of each leaflet (51) being limited by the internal configuration of each recess (59), and wherein each recess has internal wall-like portions against which facial portions of the associated ear-like projection (54) abut at the limit of closing and of opening pivotal movement of the ear-like projection.

Claims 6 and 19, see Figure 8A and column 12, lines 52-56 for the separate bearing block (58) and the bearing block receiving window (62) being associated with locating pin means (74 and 73), which cooperatively associate with one another to position and locate the separate bearing block (58) relative to the receiving window (62).

Claim 9, see Figure 2 of Bicer for the circlip (24) being cross-sectionally circular in a plane perpendicular to a central axis of the circlip.

Claims 12 and 13, see Figure 5A for in the valve closed configuration, the straight inside edge portion (75) of each said leaflet (51) is configured to seat against the other and the arcuately extending outside edge region (56) is configured to seat against adjacent side wall portions of the annular structure (50).

Claim 14, see Figure 5A and column 11, lines 33-53 for the peripheral edge portions of each of ear-like projection and interior surface portions of each of the cavities each having spherical curvatures and wherein adjacent edge portions of each of the ear-like projections is matingly engageable with the respective associated one of the cavities, whereby each ear-like projection is freely pivotable relative to the associated cavity.

Claims 15 and 16, see Figure 5A for the extent of pivotal opening and closing movement of each leaflet (51) being limited by the internal configuration of each cavity, wherein each cavity has internal wall-like portions against which facial portions of the associated ear-like projection abut at the limit of closing and of opening pivotal movement of the ear-like projection.

Claim 17, see Figures 6A and 8 for the separate bearing block (58) and the bearing block receiving window (62) each having a generally rectangular perimeter configuration.

Claim 18, see Figure 5 for in regions adjacent to the bearing block receiving window (62), the annular structure (50) is radially thickened (the annular structure has a radial thickness).

8. Claims 3 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mhatre et al. in view of Bicer.

Mhatre et al., as modified by Bicer, discloses a prosthetic heart valve assembly with a circlip with all the elements of claims 1 and 8. Neither Mhatre et al. nor Bicer disclose expressly that the circlip is comprised of non-rusting spring steel, as required by claims 3 and 10. However, in column 7, lines 1-5 of Bicer, the circlip (24) is made from a compressible and expandable material, which implies a spring material. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have the circlip of the specified material because applicant has not disclosed that the specified material provides an advantage, is used for a particular purpose, or solves a stated problem. It would have been obvious to make the circlip of a non-rusting material because it is inserted into the body. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with the circlip of other non-rusting spring materials because the ability for the circlip to retain the bearing block is not affected by the material of the circlip, as long as it is non-rusting and springy. Therefore, it would have been an obvious matter of design choice to modify Mhatre et al. and Bicer to obtain the invention as specified in claims 3 and 10.

Allowable Subject Matter

9. Claim 20 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Urmi Chattopadhyay

Art Unit 3738

David J. Isabella
Primary Examiner